

OxyContin® Study

March, 2002

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OXYCONTIN® STUDY

Executive Summary

Louisiana's 2001 Regular Legislative Session passed Senate Concurrent Resolution #58 directing the Department of Health and Hospitals to study the use, abuse, and other problems related to OxyContin®.

OxyContin® Use:

- OxyContin® tablets are a controlled-release oral formulation of oxycodone hydrochloride. OxyContin® is a prescription pain medicine that is used in the treatment of moderate to severe pain.
- OxyContin contains the drug oxycodone, which is used in pain relievers such as Percocet® and Percodan®. OxyContin® contains a higher concentration of oxycodone, because its duration of action is generally twice that of other pain relievers.
- The Comprehensive Controlled Substances Act of 1970 (CSA), placed oxycodone in Schedule II, the most stringent of Federal schedules for controlled substances approved for medical use.
- Drug Enforcement Agency (DEA) Data 2000 indicates Louisiana ranks 28th in the nation in OxyContin® consumption.

Trends:

- Studies indicate that most patients who receive opioids for pain, even those undergoing long-term therapy, do not become addicted to these drugs nor experience euphoria from drug use; although they may become physically dependent on the drug and may need to be withdrawn by a qualified physician.
- Non-medical use of prescription drugs has been increasing. Nationally, the number of new, non-medical users of prescription painkillers has increased 300% since the 1980's. National Institute of Drug Abuse (NIDA), 2001.
- Office for Addictive Disorders (OAD) Database indicates treatment admissions for "synthetic opiates and other opioids" has doubled over the past three years (FY98-99: 624, FY00-01 1230). This represents only 4% of all publicly funded treatment admissions.

OxyContin® Abuse:

- OxyContin® diversion occurs primarily through fraudulent prescriptions, doctor shopping, improper prescribing, theft from legitimate pain patients, and pharmacy theft.
- Louisiana Coroners report sixty-nine (69) deaths involving OxyContin® over from 1999-2001. Most were also associated with other drugs. In April 2000, the Louisiana State Board of Medical Examiners revised regulations governing the prescribing of controlled substances for pain.

Current Initiatives:

- Drug Enforcement Administration initiated a comprehensive effort in February 2001 to prevent the diversion of OxyContin®.
- The Industry and federal agencies have strengthened warnings and precautions for OxyContin®. Changes include a "black box warning", the strongest type of warning for an FDA-approved drug.
- The manufacturer, Purdue Pharma, has been working proactively with law enforcement and the medical community to provide education on the appropriate use of OxyContin® and has recently launched a pilot campaign in several cities to warn youth about the dangers of prescription drug abuse.

RECOMMENDATIONS:

A balanced approach must be used in dealing with the issue of all prescription drug abuse. The need to protect the public health and safety without restricting the legitimate prescribing of pharmaceutical controlled substances is essential to the effective care of patients suffering a variety of medical conditions. To ensure that legitimate users of OxyContin® continue to receive their medication while reducing its diversion and abuse, the Committee makes the following recommendations:

1. Legislation requiring the use of prescription forms containing security features for all written controlled substance prescriptions, thereby minimizing the opportunity for forgery of controlled-substance prescriptions.
2. Reinstitute the Drug Policy Board committee for prescription accountability and patient care monitoring. Develop a statewide electronic prescription monitoring program with enabling legislation to implement such programs consistent with the Model Prescription Accountability Act. The goals would be to:
 - Limit access only to those with legitimate medical need;
 - Establish the ability to identify and track instances in which controls are compromised; and
 - Identify potential controlled substance abusers and steer them to treatment.
3. Adopt a Resolution requiring Licensing Boards of those persons who prescribe or dispense controlled dangerous substances to include a requirement of continuing medical education programs addressing proper pain management and addictive disorders.
4. Increase funding to be utilized for the treatment and prevention of prescription drug addiction.

OXYCONTIN STUDY

I. Introduction

- Louisiana's 2001 Regular Legislative Session passed Senate Concurrent Resolution #58 directing the Department of Health and Hospitals to study the use, abuse, and other problems related to OxyContin®.
- Oxycodone abuse has been a continuing problem in the United States since the early 1960's.
- The Comprehensive Controlled Substances Act of 1970 (CSA), placed oxycodone in Schedule II, the most stringent of Federal schedules for controlled substances approved for medical use.
- For purposes of this Study the following definitions shall apply:
 - Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: Impaired control over drug use, compulsive use, continued use despite harm, and craving.
 - Physical Dependence is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
 - Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

II. Description of OxyContin® Use

- OxyContin® is a prescription pain medicine that is used in the treatment of moderate to severe pain.
- OxyContin® tablets are a controlled-release oral formulation of oxycodone hydrochloride.
- OxyContin® contains the drug oxycodone, which is used in pain relievers such as Percocet® and Percodan®. However, OxyContin® is a sustained, controlled-release formulation and contains a higher concentration of oxycodone with duration of action generally twice that of other pain relievers.
- The drug is a central nervous system depressant, with possible effects being analgesia, respiratory depression, and euphoria.
- Studies indicate that most patients who receive opioids for pain, even those undergoing long-term therapy, do not become addicted to these drugs nor experience euphoria from drug use; although they may become physically dependent on the drug and may need to be withdrawn by a qualified physician.

III. Description of OxyContin® Abuse

- Two primary factors set OxyContin® abuse apart from other prescription drug abuse: OxyContin® abusers often crush the tablet and ingest or snort it, or dilute it in water and inject it. Both methods lead to the rapid release and absorption of oxycodone.
- Crushing or diluting the tablet disarms the timed-release action causing rapid release of a 12-hour supply of the drug resulting in a quick, powerful high. Abusers have compared this feeling to the euphoria they experience when taking heroin.
- The illegal sale of OxyContin® is profitable. A 40-milligram pill costs approximately \$4 by prescription, yet it has a street value of \$20-\$40 per tablet when sold illegally.

- OxyContin® is obtained for illicit purposes through theft, including stealing from someone with a legitimate prescription, prescription forgery, doctor shopping (with or without legitimate ailments), and improper prescribing.
- Initially, the following states reported OxyContin® abuse: Maine, Virginia, West Virginia, Ohio, Kentucky, and Maryland; however, the problem has now expanded throughout the United States.
- Indicators used to produce the Drug Abuse Warning Network (DAWN) study show that the abuse of oxycodone products has increased greatly over the past three years.
- Most people, who take OxyContin®, as prescribed under a physician's care, do not become addicted. However, OxyContin®, like morphine, has a high potential for abuse.

IV. National Trends

- Non-medical use of prescription drugs has been increasing across the country. Nationally, the number of new, non-medical users of prescription painkillers has increased 300% since the 1980's. National Institute of Drug Abuse (NIDA), 2001
- According to the DAWN Report, emergency department mentions of the synthetic opiate, oxycodone, increased 68 percent between 1999 and 2000.
- In 1999, medical examiners participating in the DAWN study reported 262 mentions of oxycodone-related deaths.
- Opiates as primary drugs of abuse continue to account for relatively small proportions of drug treatment admissions (0-3%). Community Epidemiology Work Group (CWEG) NIDA, June 2001
- The top four drugs identified in the National Forensic Laboratory Information System (NFLIS) Report, 2000, are Cannabis, Cocaine, Methamphetamine, and Heroin.
 - Oxycodone ranks in the top 25 most frequently identified substances.
 - Of the *analgesics* analyzed, oxycodone made up approximately 28%.
 - In the South, oxycodone is identified in less than 1% (0.67%) of the total analyzed items.

V. Oxycontin® in Louisiana

- Drug Enforcement Agency (DEA) Data 2000 indicates Louisiana ranks 28th in the nation in OxyContin® consumption. Average use is 3653 grams per 100,000 population compared to the national average of 3590 grams per 100,000.
- DHH Medical Assistance Program tracks the use of OxyContin®, as well as other brand name drugs, among those clients receiving Medicaid drug benefits.

Total Number of Louisiana Medicaid Eligible Recipients: 819,440 <i>July 1, 2000-June 30, 2001</i>		
Drug	Recipients	Percentage of Total Recipients
Narcotic Analgesics	171,296	21%
Oxycodone	28,550	3%
OxyContin®	5307	1%
Number of Prescribers of Oxycodone 6108		

- Office for Addictive Disorders (OAD) Database indicates treatment admissions for "synthetic opiates and other opioids" has doubled over the past three years (FY98-99: 624, FY00-01: 1230). This still represents only 4% of all publicly funded treatment admissions.
- Oxycodone ranked 11th of the drugs most frequently identified by Forensic Laboratories (Louisiana State Epidemiology Report, 2000)

- Louisiana Coroners report sixty-nine (69) deaths involving OxyContin® over the past two years. Most were also associated with other drugs.

OxyContin Related Deaths
Reported by Louisiana Coroners
1999-2001

Parish	Number of Deaths
Calcasieu	18
Jefferson	15
St. Bernard	8
Orleans	5
St. Tammany	4
Winn	3
St. Landry	3
Lafayette	2
Ouachita	2
Plaquemines	2
Concordia	2
Bossier	1
Jefferson Davis	1
St. Charles	1
Tangipahoa	1
Washington	1
Acadia, Allen, Ascension, Assumption, Beauregard, Bienville, Caldwell, Cameron, Catahoula, Claiborne, DeSoto, East Baton Rouge, East Feliciana, Evangeline, Franklin, Grant, Iberia, Iberville, Jackson, Lafourche, Lincoln, Madison, Morehouse, Natchitoches, Pointe Coupee, Richland, Sabine, St. James, St. John the Baptist, St. Martin, St. Mary, Tensas, Terrebonne, Union, Vermilion, Webster, West Baton Rouge, West Carroll, West Feliciana	0
*Total	69

***Nine (9) Parishes did not report. They are as follows:**

Avoyelles, Caddo, East Carroll, LaSalle, Livingston, Rapides, St. Helena, Vernon, Red River.

- According to the DEA New Orleans Diversion Group, the total number of Louisiana pharmacy thefts reported in 2000 was 186. Of the 186 thefts, seventeen (17) or nine percent (9%) involved OxyContin®.

VI. Findings:

- OxyContin® diversion occurs primarily through fraudulent prescriptions, doctor shopping, improper prescribing, theft from legitimate pain patients, and pharmacy theft.
- OxyContin® is the current prescription drug of abuse getting media attention.
 - Hydrocodone (Vicodin®, Lortab®) has long been the number one prescription drug of abuse, and usually overshadows the oxycodone products.
 - Benzodiazepines (Valium®, Xanax®) are another significant source of abuse.

- The diversion and abuse of prescription drugs is a serious public health concern. The true extent of the problem is difficult to measure without a system for reporting or a monitoring program.
- One strategy to reduce diversion is the implementation of a prescription monitoring program.
 - Monitoring can identify patients who forge prescriptions or con unsuspecting doctors and doctors who indiscriminately prescribe narcotics.
 - 18 states have implemented legislation or statutory regulations for prescription monitoring programs. Law enforcement officials report that states with good monitoring programs have little OxyContin® abuse, while states without them have increased incidents.
 - Louisiana, under the direction of the Attorney General who was at that time also chairman of the Drug Policy Board, held a Model Drug Law Summit in 1996 and explored the possibility of implementing a prescription monitoring program. Due to change in leadership, policy shifts and new priorities, the Prescription Study Resolution was not presented to the legislature.
- The answers to reducing OxyContin® abuse are the same answers for reducing prescription drug abuse in general. Education should be one of the top priorities for the general public, law enforcement, and most importantly, health care professionals who prescribe controlled substances.
- States need the ability to stop illegal diversion of prescription drugs in an efficient and cost-effective manner, without impeding the appropriate prescribing of pain-killing and other prescription drugs or compromising patients' interests in confidentiality.
- Legislative initiatives throughout the country are being drafted to make illicit OxyContin® distribution less appealing by creating more stringent penalties.
- There is a need for increased treatment capacity. Current funding only meets 8% of the identified need for addiction treatment in the State.
- Treatment documented as effective for opioid addiction includes:
 - 1. Detoxification services
 - 2. Long term Residential treatment, and when indicated,
 - 3. Medication assisted outpatient treatment

VII. CURRENT INITIATIVES:

- In response to increased concern among federal, state, and local officials about the dramatic increase in the illicit availability and abuse of the prescription drug OxyContin®, the Drug Enforcement Administration (DEA) initiated a comprehensive effort in February, 2001 to prevent the diversion of OxyContin® and reverse this trend.
- The Industry and federal agencies have strengthened warnings and precautions for OxyContin®. New labeling is intended to change prescription practices as well as increase the physicians' focus on the potential for abuse, misuse, and diversion. Changes include a "black box warning", the strongest type of warning for an FDA-approved drug.
- The U.S. Department of Health and Human Services has disseminated Clinical Practice Guidelines for the management of acute pain and cancer pain.
- In April 2000, the Louisiana State Board of Medical Examiners revised regulations governing the prescribing of controlled substances for pain. The new regulations outline standards of medical practice in the treatment of pain. This includes assessment and evaluation of the patient to develop the treatment plan with periodic review, documentation and consultation in order to assure that the patient is provided with quality care.

- The manufacturer, Purdue Pharma, has been working proactively with law enforcement and the medical community to provide education on the appropriate use of OxyContin[®] and has recently launched a pilot campaign in several cities to warn youth about the dangers of prescription drug abuse.

VIII. RECOMMENDATIONS:

A balanced approach must be used in dealing with the issue of all prescription drug abuse. The need to protect the public health and safety without restricting the legitimate prescribing of pharmaceutical controlled substances is essential to the effective care of patients suffering a variety of medical conditions. To ensure that legitimate users of OxyContin[®] continue to receive their medication while reducing its diversion and abuse, the Committee makes the following recommendations:

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The goals would be to:

- Limit access only to those with legitimate medical need;
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3. Adopt a Resolution requiring Licensing Boards of those persons who prescribe or dispense controlled dangerous substances to include a requirement of continuing medical education programs addressing proper pain management and addictive disorders.
 4. Increase funding to be utilized for the treatment and prevention of prescription drug addiction.

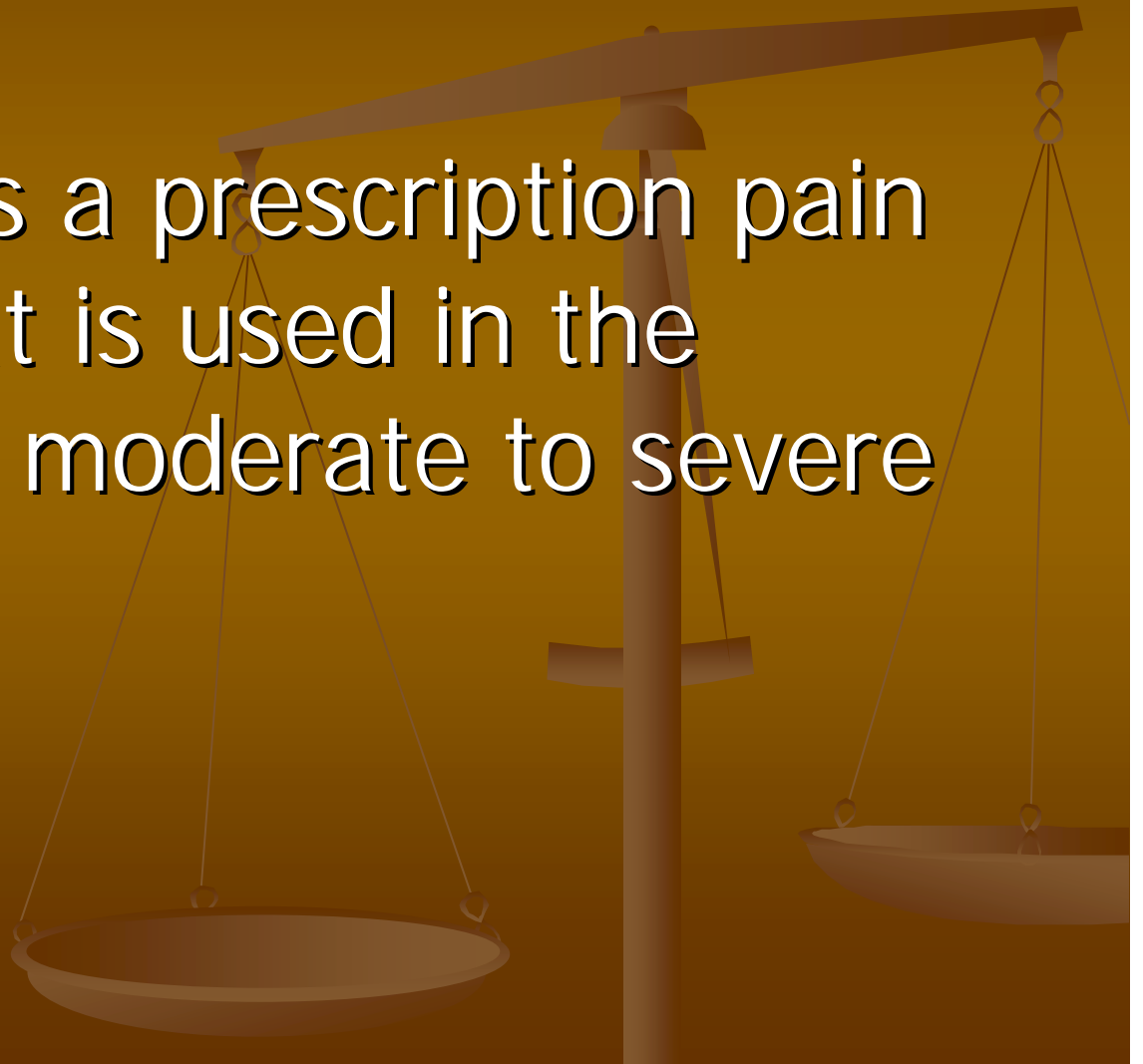


OxyContin[®] Study Per Senate Concurrent Resolution 58

State of Louisiana
Department of Health and Hospitals
Office for Addictive Disorders
March 12, 2002

What is OxyContin[®]?

OxyContin[®] is a prescription pain medicine that is used in the treatment of moderate to severe pain.



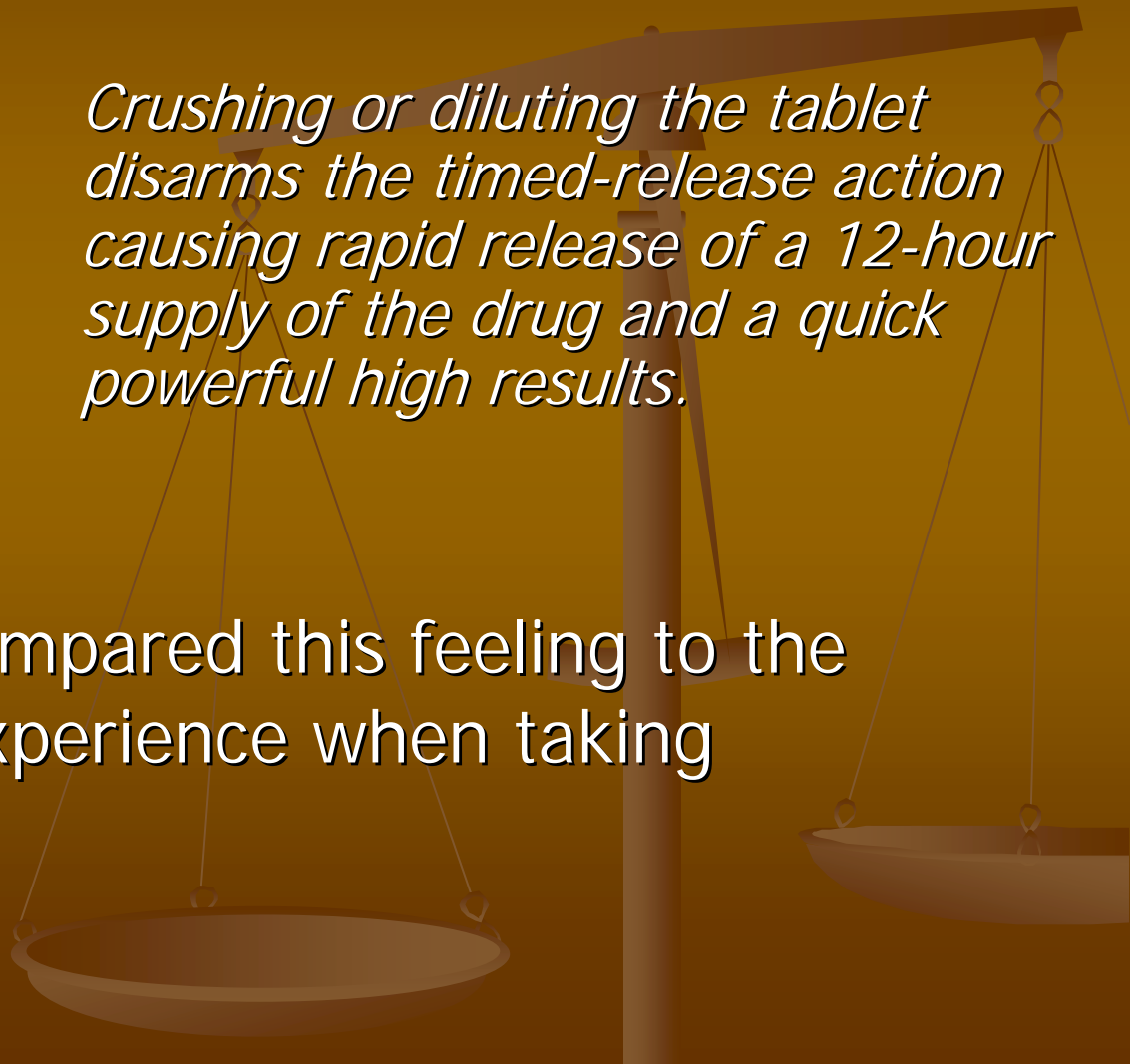
What Makes OxyContin[®] Different?

■ Abuse

- Crush
- Snort
- Inject

Crushing or diluting the tablet disarms the timed-release action causing rapid release of a 12-hour supply of the drug and a quick powerful high results.

Abusers have compared this feeling to the euphoria they experience when taking heroin.



What Makes OxyContin[®] Different?

Prescription Cost of
40 mg OxyContin[®] =

\$4.00

Street Value =

\$20-\$40

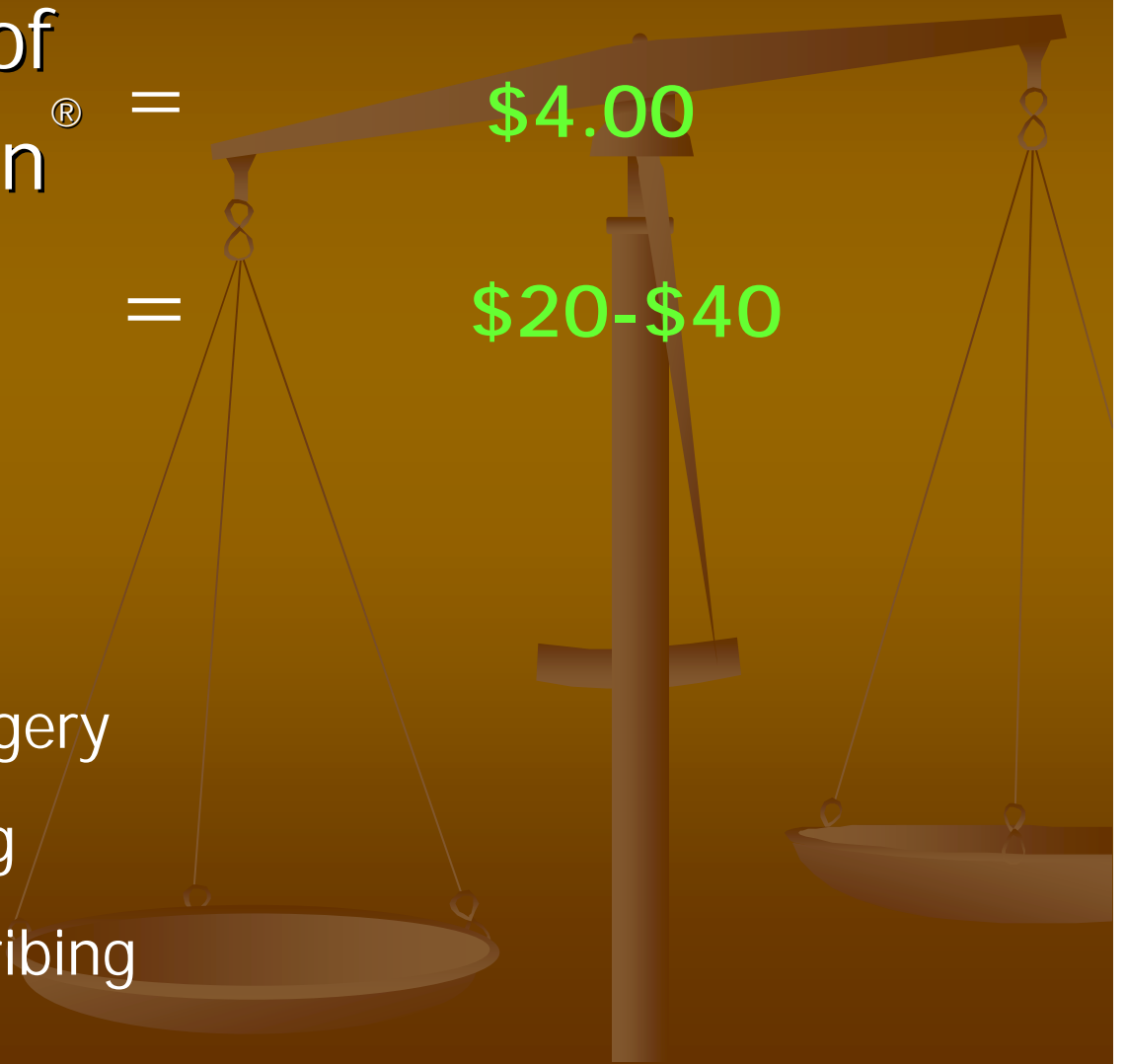
Methods of Obtaining:

Theft

Prescription Forgery

Doctor Shopping

Improper Prescribing



Addiction

Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations.

It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

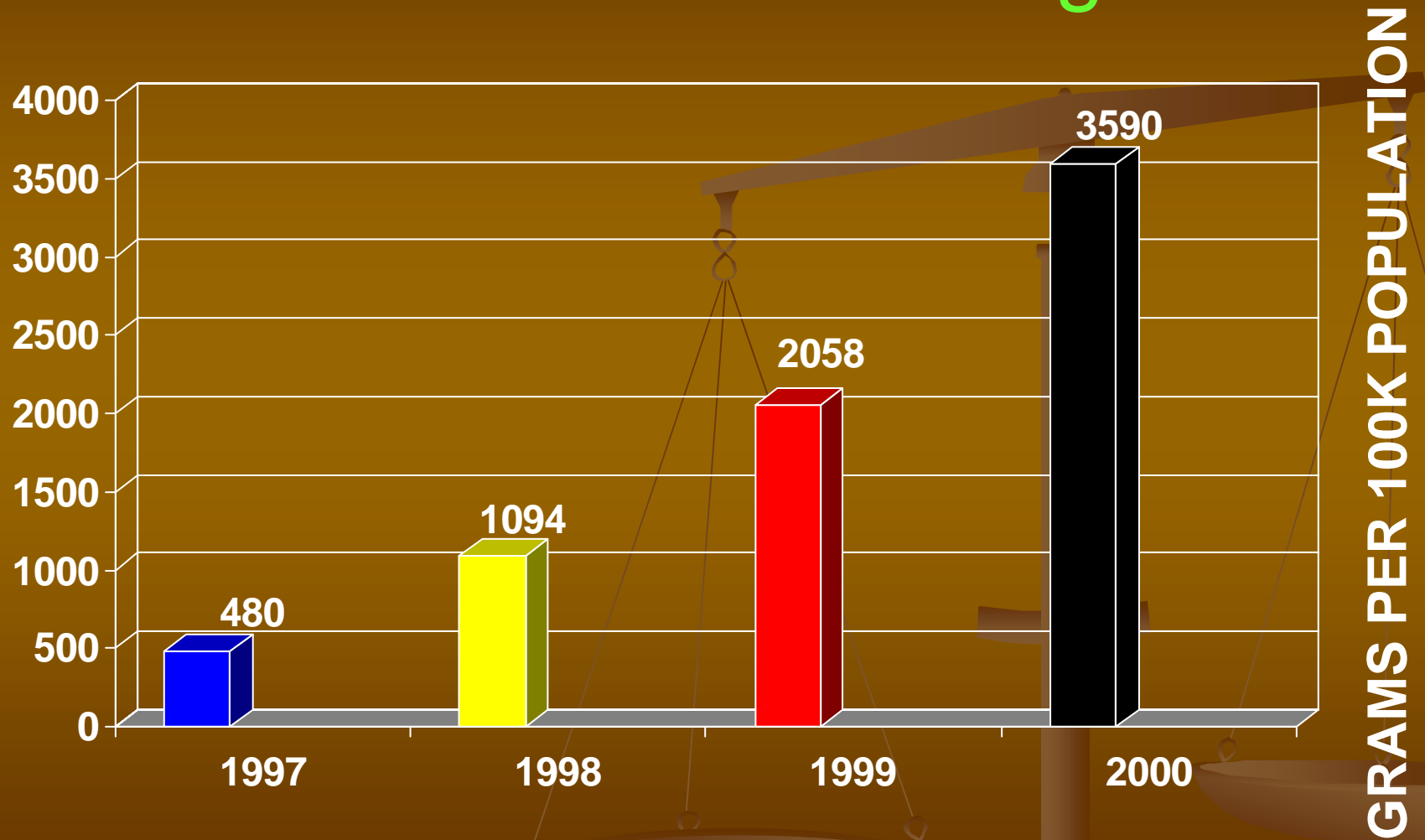
Approved by the Boards of Directors of the AAPM, APS, and ASAM, February 2001

National Trends

- Non-medical use of prescription drugs has been increasing across the country.
- Nationally, the number of new, non-medical users of prescription painkillers has increased 300% since the 1980's.

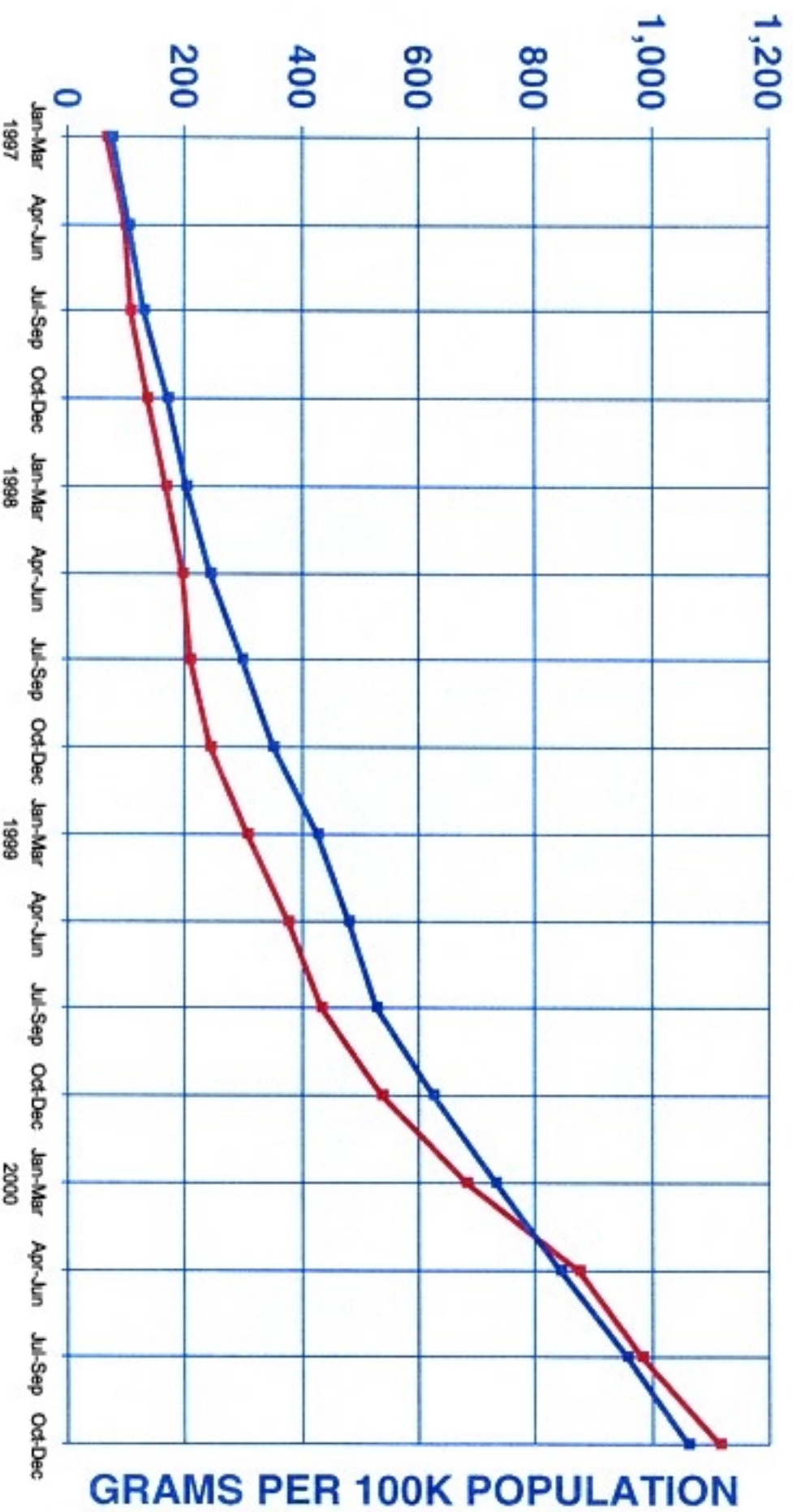
National Institute of Drug Abuse (NIDA), 2001

OxyContin[®] Consumption* 1997-2000 U.S. Average



*Excludes Mail Order Pharmacies

State of Louisiana 1997-2000 OxyContin Consumption*



* Excludes Mail Order Pharmacies

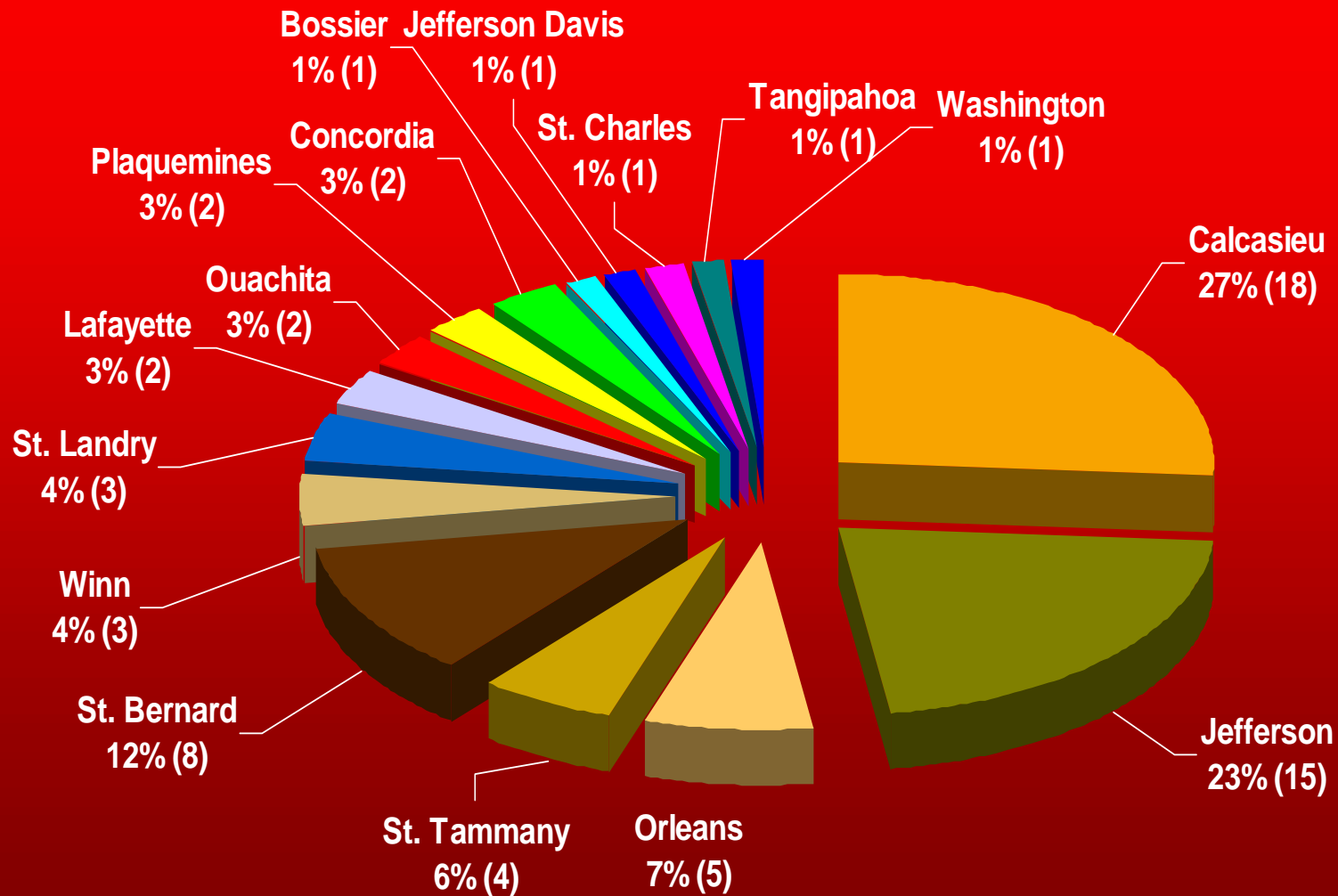
LA Average U.S. Average

OxyContin[®] in Louisiana

Total Number of Louisiana
Medicaid Eligible Recipients: 819,440
July 1, 2000-June 30, 2001

<u>Drug</u>	<u>Recipients</u>	<u>Percentage of Total Recipients</u>
Narcotic Analgesics	171,296	21%
Oxycodone	28,550	3%
OxyContin [®]	5,307	1%
Number of Prescribers of Oxycodone: 6,108		

Coroner's Report



Total Deaths = 69

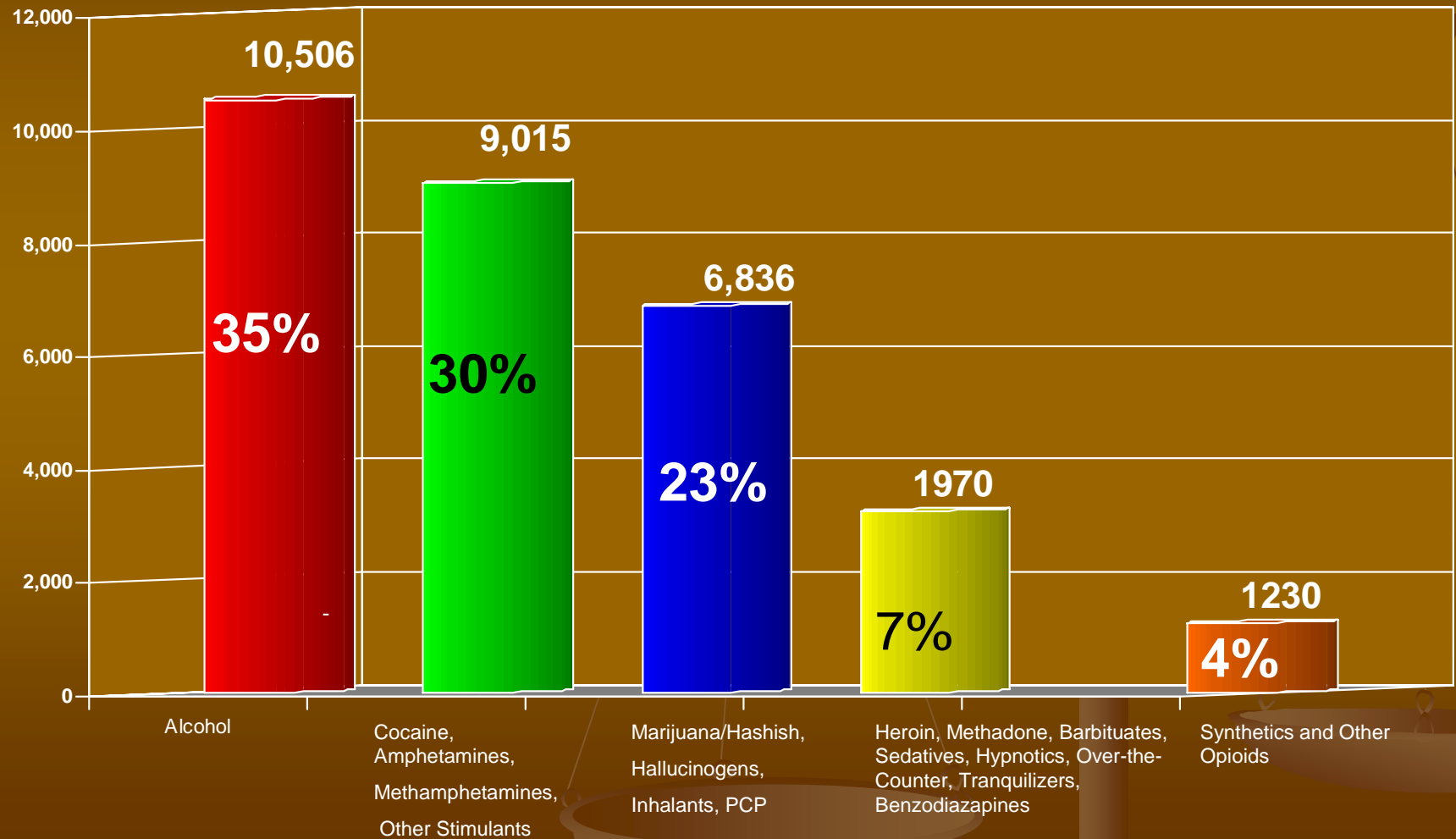
Nine Parishes did not report—all other Parishes reported zero deaths.

OxyContin[®] in Louisiana Pharmacy Thefts 2000

- Total: 186
- Oxycontin[®] Involved: 17
- Percentage of Total: 9%

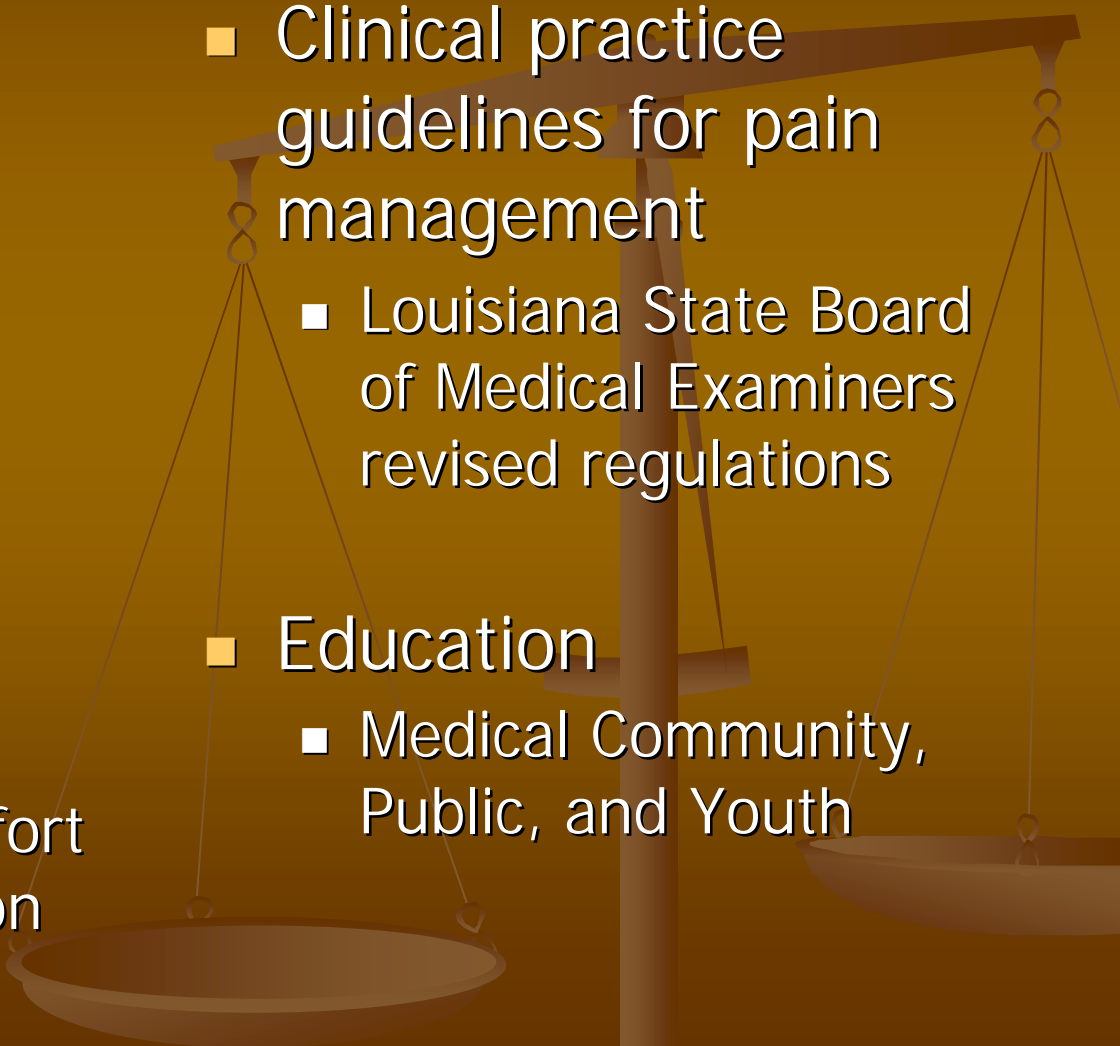


30,279 Admissions by Primary Addiction Type FY 2000-2001



OxyContin[®]

Current Initiatives

- 
- Strengthened warnings and precautions
 - Clinical practice guidelines for pain management
 - Louisiana State Board of Medical Examiners revised regulations
 - Drug Enforcement Agency
 - Comprehensive effort to prevent diversion
 - Education
 - Medical Community, Public, and Youth


OxyContin[®] in Louisiana Recommendations

1. Prescription forms with security features
2. Prescription monitoring and accountability
3. Continuing education
4. Treatment and Prevention



Tamper-Resistant Pad

■ AN ARTIFICIAL WATERMARK IS ON THE BACK - HOLD AT AN ANGLE TO VIEW THIS MARK ■

 **Standard Register Medical Center**
1234 Document Avenue
City, State 00000
Ph. 123-456-0000 • Fax 123-456-0001

02770531

PATIENT'S FULL NAME	PHONE NUMBER	AGE	SEX
ADDRESS		DATE / /	

R_x

VOID

Dr. _____ Dr. _____
DISPENSE AS WRITTEN PRODUCT SELECTION PERMITTED

☐ Refills 1 2 3 4 _____
☐ No Refills Void After _____

DEA #: 780978097890

VALID FOR CONTROLLED SUBSTANCES

■ "RX" ON BACK IS PRINTED IN DISAPPEARING INK - RUB BRISKLY TO ACTIVATE ■

Standard Register Medical Center
ARTIFICIAL WATERMARK - HOLD AT AN ANGLE TO VIEW THIS MARK

Purdue Pharma's 10-Point Plan to Reduce Prescription Drug Abuse

Without Compromising Patient Access to Proper Pain Control

Prescription drug abuse is a serious public health problem in the United States. It affects some 4 million Americans—more than those who abuse cocaine and heroin combined. Purdue Pharma L.P., a leading manufacturer of prescription pain medications, has made a commitment to help reduce prescription drug abuse with a multifaceted program of prevention and education. Our 10-point plan includes the following initiatives:



3 DRUG PREVENTION AND EDUCATION PROGRAMS FOR "TWENTYS"

A series of public service announcements is now running in areas of highest drug abuse, and Purdue is working with the Community Anti-Drug Coalitions of America to develop new educational programs to alert the vulnerable "twentys" population (ages 18-22) about the dangers of abusing prescription medications.

4 OPIOID DOCUMENTATION KITS

are being offered to help physicians assess pain properly and distinguish between legitimate patients suffering from pain and those pretending to be in pain in order to obtain controlled substances.

5 ABUSE AND DIVERSION BROCHURES

have been mailed to nearly 500,000 physicians and more than 60,000 pharmacists throughout the country, providing valuable information on how they can help prevent diversion of prescription drugs.



6 A MAJOR STUDY OF PRESCRIPTION MONITORING PROGRAMS

is being undertaken by Purdue. Working with the healthcare and law enforcement communities, the study will seek to develop a model prescription monitoring program that would prevent "doctor shopping" by drug abusers without interfering with the ability of legitimate patients to receive appropriate prescription medicines.

7 EDUCATIONAL PROGRAMS WITH LAW ENFORCEMENT COMMUNITY

including the National Association of Drug Diversion Investigators (NADDI), several State Attorneys General and the National Association of State Controlled Substance Authorities (NASCSA), to better understand the undertreatment of pain and explore new approaches to combat prescription drug abuse.

8 RESEARCH on the prevalence and root cause of the abuse of specific prescription drugs is being collected by Purdue-sponsored researchers, so that more effective prevention programs can be developed and evaluated.



9 CROSS-BORDER SMUGGLING is being addressed, in cooperation with the DEA, to prevent our products from being smuggled into the U.S. from Mexico and Canada. Tablets sold in Mexico and Canada will have unique markings to enable law enforcement to identify where the product was dispensed.

10 ABUSE-RESISTANT MEDICINES

are the number one priority in our research labs. Purdue is spending millions of dollars to test and develop new forms of pain relievers that would be resistant to abuse while providing safe and effective pain relief to legitimate patients.

Solving the public health problem of prescription drug abuse will require the cooperation of many elements of our society—law enforcement, schools, parents, religious organizations, healthcare providers, social service agencies, regulatory bodies, and the pharmaceutical industry. Purdue is taking the lead within our industry in addressing this critical social problem because we believe it is the right thing to do.

Looking ahead, we are working on a predictive model that will help us identify areas where drug abuse might spread. Based on this analysis, we will intensify our education and prevention activities in those regions of the country.

We are deeply troubled by the human tragedy of prescription drug abuse and are doing our part to help. We are also firmly committed to keeping pain-relieving medicines available for the millions of legitimate patients who need them most.

We will not let patients suffer in silence. We are committed to being true partners against pain®.



www.painpartnersagainstpain.com

Addiction in Louisiana

Identified Need vs. Unmet Need

Service Type	Identified Need	Need Met by OAD Admissions	% in Need of Treatment
Adults	318,857	27,707 (9%)	91%
Adolescents	56,702	2,572 (4.5%)	95.5%
Gambling	53,000	720 (1%)	99%
All Admissions	375,559	30,279 (8%)	92%
Prevention	1,343,190	250,000 (18%)	82%

Office for Addictive Disorders OxyContin® Study Committee	
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**Office for Addictive Disorders
OxyContin® Study Committee**

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